IN THE UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re: NEXIUM (ESOMEPRAZOLE) ANTITRUST LITIGATION This Document Relates to: All End-Payor Actions	MDL No. 2409 Civil Action No.: 1:12-md-2409-WGY

CONSOLIDATED AMENDED CLASS ACTION COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiffs United Food and Commercial Workers Unions and Employers Midwest Health Benefits Fund, Allied Services Division Welfare Fund, Fraternal Order of Police Miami Lodge 20, Insurance Trust Fund, New York Hotel Trades Council & Hotel Assoc. of New York City, Inc. Health Benefits Fund, Laborers International Union of North America Local 35 Health Care Fund, International Brotherhood of Electrical Workers Local 595 Health and Welfare Fund, Laborers International Union of North America Local 17 Health Care Fund, International Union of Machinists and Aerospace Workers District No. 15 Health Fund, Michigan Regional Council of Carpenters Employee Benefits Fund, and A.F. of L. – A.G.C. Building Trades Welfare Plan (collectively "Plaintiffs") on behalf of themselves and all others similarly situated, file this Consolidated Amended Class Action Complaint ("Complaint") against Defendants AstraZeneca AB, Aktiebolaget Hassle, AstraZeneca LP (collectively "AstraZeneca"), Ranbaxy Pharmaceuticals, Inc., Ranbaxy Inc. and Ranbaxy Laboratories Ltd. (collectively, "Ranbaxy"), Teva Pharmaceutical Industries, Ltd., Teva USA, Inc. (collectively, "Teva"), Dr. Reddy's Laboratories Ltd., and Dr. Reddy's Laboratories, Inc. (collectively, "Dr. Reddy's") (together the "Generic Defendants," and together with AstraZeneca, the "Defendants"), based upon personal

knowledge as to facts pertaining to it, and upon information and belief as to all other matters, and alleges as follows:

NATURE OF THE ACTION

1. This action arises out of Defendants' overarching scheme to unreasonably restrain trade in and monopolize the market for delayed-release esomeprazole magnesium, sold by AstraZeneca under the brand name Nexium. Nexium is a proton pump inhibitor prescribed to patients for the healing of erosive esophagitis, maintenance of erosive esophagitis, and treatment of symptomatic gastroesophageal reflux disease. By entering into illegal market allocation conspiracies with, between and among the Generic Defendants, AstraZeneca has prevented any generic delayed-release esomeprazole magnesium product from entering the market in competition with Nexium.

2. To protect its over $3 billion in annual Nexium sales from the threat of generic competition, AstraZeneca entered into non-competition agreements with each of the Generic Defendants, agreeing to pay the Generic Defendants substantial sums in exchange for their agreement to delay marketing their less expensive generic versions of Nexium for as many as six years or more, *i.e.*, until May 27, 2014 (the "Exclusion Payment Agreements" or simply the "Agreements"). The Generic Defendants did, in fact, delay marketing their less-expensive versions of Nexium; but for the Agreements, generic versions of Nexium would have been available to Plaintiff and members of the Class in the United States as early as April 14, 2008, when the 30-month stay of FDA approval of Ranbaxy's generic Nexium product expired.

3. Generic versions of brand name drugs contain the same active ingredient, and are determined by the Food and Drug Administration ("FDA") to be just as safe and effective as their brand name counterparts. The only material difference between generic and brand name drugs is their price: generics are usually at least 25% less expensive than their brand name

counterparts when there is a single generic competitor, and this discount typically increases to 50% to 80% (or more) when there are multiple generic competitors on the market for a given brand. The launch of a generic drug thus usually brings huge cost savings for all drug purchasers.

4. Those same savings are viewed as a grave threat by brand name drug companies such as AstraZeneca. The Federal Trade Commission estimates that about one year after market entry, the generic version takes over 90% of the brand's unit sales and sells for 15% of the brand's price.

5. In order to delay the drastic loss of its monopoly profits from Nexium, AstraZeneca engineered an overarching scheme whereby it would buy its way out of both competition with the Generic Defendants and the chance that its Nexium patents would be invalidated. Specifically, AstraZeneca agreed to pay the Generic Defendants to defer entering the market until May 27, 2014 and to drop their challenges to the Nexium patents. AstraZeneca and the Generic Defendants attempted to disguise these payments (frequently called "Exclusion Payments" or "Reverse Payments") as payments to compensate them for: (i) supplying a portion of AstraZeneca's Nexium supply, including esomeprazole magnesium, the active pharmaceutical ingredient ("API") in Nexium, for distributing authorized generic versions of two other AstraZeneca drugs, felodipine capsules (brand name, Plendil) and 40 mg omeprazole tablets (brand name, Prilosec) (with respect to Ranbaxy); or (ii) forgiveness of a contingent liability (with respect to Teva and Dr. Reddy's). AstraZeneca also provided substantial compensation to Ranbaxy by agreeing not to launch its own authorized generic version of Nexium in competition with Ranbaxy's generic Nexium product for at least the first 180 days after Ranbaxy's launch.

Defendants intentionally concealed the true purpose and nature of their exclusion payments, in an attempt to escape liability under the antitrust laws.

6. Although the Exclusion Payment Agreements purported to settle patent infringement suits that AstraZeneca filed against the Generic Defendants with respect to patents that purportedly cover Nexium, AstraZeneca used the strength of its wallet as opposed to the strength of its patents to obtain the Generic Defendants' agreement not to launch their generic Nexium products. In light of the substantial possibility that AstraZeneca's Nexium patents would be invalidated and/or that the Generics' products would be adjudged non-infringing—in which case AstraZeneca would have been unable to keep generic versions of Nexium from swiftly capturing the vast majority of Nexium sales—AstraZeneca agreed to share its monopoly profits with the Generic Defendants as the *quid pro quo* for the Generic Defendants' agreement not to compete with AstraZeneca in the delayed-release esomeprazole magnesium market until May 27, 2014.

7. The Generic Defendants knew that it would be more profitable to be paid not to compete than to enter the market. Had the Generic Defendants all launched generic versions of Nexium, as they were preparing and poised to do, the competition among them would have driven down the price of generic Nexium. Once there are multiple generic versions of the same brand drug available, the generic behaves like a commodity, with little to distinguish one generic from another except price. While such competitive generic sales are still profitable, it can be more profitable to be paid by the brand company not to compete. The Generic Defendants were well aware of these market dynamics, and knew that, rather than entering the market and competing, they could make a larger profit by agreeing to delay entry in exchange for a portion

of AstraZeneca's monopoly profits from Nexium, paid in the form of an Exclusion Payment. And that is precisely what happened.

8. AstraZeneca and Ranbaxy also knew and intended that their Exclusion Payment Agreement would prevent still other generic companies from launching their own generic Nexium before Ranbaxy did, thereby creating a bottleneck. As the first filer of an Abbreviated New Drug Application ("ANDA") for generic Nexium, Ranbaxy is entitled to market its generic Nexium for 180 days free from competition from other generic Nexium products. The operation of the Exclusion Payment Agreement between AstraZeneca and Ranbaxy can block any other generic Nexium products from coming to market until 180 days after May 27, 2014 because, absent circumstances discussed below, FDA will not approve subsequently-filed ANDAs until the first-filer's exclusivity period has run, which will not occur until 180 days after Ranbaxy launches. The Agreement also blocks an authorized generic version of Nexium from entering the market until that same time, because as consideration for Ranbaxy's agreement to stay out of the market until May 27, 2014, AstraZeneca agreed not to launch an authorized generic Nexium product until, at a minimum, the end of Ranbaxy's 180-day exclusivity.

9. Although it is possible that Ranbaxy could forfeit its 180-day exclusivity if it does not begin commercial marketing of its generic Nexium products within 75 days of a court decision that all of the patents listed in the FDA's book of Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the "Orange Book," for Nexium are invalid or not infringed, AstraZeneca made sure that the second and third ANDA-filers for Nexium—Teva and Dr. Reddy's—would not break the bottleneck caused by its Exclusion Payment Agreement with Ranbaxy by obtaining such a court decision. When Teva and Dr. Reddy's neared a court determination on the issue of invalidity and/or non-infringement of the

Nexium patents, AstraZeneca paid them too, pursuant to the Exclusion Payment Agreements, to drop their patent challenges and stay out of the market until after Ranbaxy was permitted to enter the market under Ranbaxy's Exclusion Payment Agreement with AstraZeneca.

10. But for one or more of the unlawful Agreements alleged herein, generic versions of Nexium would have entered the market as early as April 14, 2008, after the 30-month stay of FDA approval of Ranbaxy's Nexium products expired. FDA had granted tentative approval to Ranbaxy's Nexium product on February 5, 2008, which, absent the illegal Agreements complained of herein, would have been converted to a final approval on or about April 14, 2008. Thus, absent Defendants' illegal Agreements not to compete, Plaintiff and the members of the Class would have already been able to purchase, and would have purchased, generic delayed-release esomeprazole magnesium at significantly lower prices, rather than being forced to pay high prices for branded Nexium.

11. Defendants' unlawful Exclusion Payment Agreements were designed to and did in fact: (a) preclude the entry of less expensive generic versions of delayed-release esomeprazole magnesium in the United States; (b) fix, raise, maintain or stabilize the price of delayed-release esomeprazole magnesium products; (c) permit AstraZeneca to maintain a monopoly in the United States for delayed-release esomeprazole magnesium; and (d) allocate 100% of the United States delayed-release esomeprazole magnesium market to AstraZeneca.

12. This action is brought as a class action on behalf of all consumers and third-party payors (collectively "End-Payor Class") in the certain States and Puerto Rico who purchased or paid for branded and/or generic Nexium products, other than for re-sale, since April 14, 2008 (*see* Class Definition below). Plaintiffs seek a judgment declaring that Defendants' overarching scheme, including the Exclusion Payment Agreements, as further described below, is unlawful

under Section 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2. Plaintiffs also seek an injunction pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, enjoining the continuation of the anti-competitive Agreements. Unless enjoined, Defendants' unlawful conduct will continue unchecked and Plaintiffs and the End-Payor Class will continue to bear the financial brunt of Defendants' antitrust violations.

13. Plaintiffs also assert claims for compensatory and/or treble damages and equitable relief for continuing violations of the State laws enumerated below.

PARTIES

A. Plaintiffs

14. Plaintiff United Food and Commercial Workers Unions and Employers Midwest Health Benefits Fund ("UFCW") is an employee welfare benefit plan. UFCW's office, from which it pays medical benefits including benefits for prescription drugs, is located in Cook County, Illinois. UFCW has purchased Nexium, other than for re-sale (and will purchase generic Nexium other than for re-sale once it becomes available), at supra-competitive prices during the Class Period, and has thereby been injured.

15. Plaintiff Allied Services Division Welfare Fund ("ASD") is a health and welfare benefit fund with its principal place of business at 53 West Seegers Road, Arlington Heights, Illinois 60005, and is involved in the business of providing health and pension benefits, among others, to covered lives. ASD has purchased Nexium, other than for re-sale (and will purchase generic Nexium other than for re-sale once it becomes available), at supra-competitive prices during the Class Period, and has thereby been injured.

16. Plaintiff Fraternal Order of Police Miami Lodge 20, Insurance Trust Fund ("FOP") is a governmental plan established and funded through contributions from the City of Miami and the plan's members, who are current and retired sworn officers of the City of Miami

Police Department and their dependents. FOP was established pursuant to a duly executed Trust Agreement for the purpose of providing medical, surgical and hospital care or benefits, including prescription drug benefits, to its members. FOP maintains its principal place of business 400 NW 2nd Avenue, Miami, Florida and, thus, is a citizen of Florida. FOP has purchased Nexium, other than for re-sale (and will purchase generic Nexium other than for re-sale once it becomes available), at supra-competitive prices during the Class Period, and has thereby been injured.

17. Plaintiff New York Hotel Trades Council & Hotel Assoc. of New York City, Inc. Health Benefits Fund ("NYHTC") is a jointly-trusteed employee benefits fund which operates for the benefit of active and retired unionized hotel workers in the New York metro area. NYHTC has its principal place of business at 305 West 44th Street, New York, New York, 10036 and, thus, is a citizen of New York. NYHTC has purchased Nexium, other than for re-sale (and will purchase generic Nexium other than for re-sale once it becomes available), at supra-competitive prices during the Class Period, and has thereby been injured.

18. Plaintiff Laborers International Union of North America Local 35 Health Care Fund ("Local 35 Health Care Fund") is involved in the business of providing health and welfare benefits, among others, to covered lives. Local 35 Health Care Fund has purchased Nexium, other than for re-sale (and will purchase generic Nexium other than for re-sale once it becomes available), at supra-competitive prices during the Class Period, and has thereby been injured.

19. Plaintiff International Brotherhood of Electrical Workers Local 595 Health and Welfare Fund ("IBEW 595 Fund") is a trust fund/employee benefit plan organized under the laws of the United States for the sole and exclusive purpose of providing health and welfare benefits to current, former and retired IBEW 595 union members, and to their dependents and beneficiaries. The IBEW 595 Fund's principal place of business is in Pleasanton, California.

IBEW 595 Fund has purchased Nexium, other than for re-sale (and will purchase generic Nexium other than for re-sale once it becomes available), at supra-competitive prices during the Class Period, and has thereby been injured.

20. Plaintiff Laborers International Union of North America Local 17 Health Care Fund ("Local 17 Health Care Fund") is involved in the business of providing health and welfare benefits, among others, to covered lives. Local 17 Health Care Fund has purchased Nexium, other than for re-sale (and will purchase generic Nexium other than for re-sale once it becomes available), at supra-competitive prices during the Class Period, and has thereby been injured.

21. Plaintiff International Union of Machinists and Aerospace Workers District No. 15 Health Fund ("IAM 15") is a jointly-trusteed employee health fund which operates for the benefit of active and retired machinists and aerospace workers in the New York/New Jersey metro areas. IAM 15 has its principal place of business at 140 Sylvan Avenue, Suite 303, Englewood Cliffs, New Jersey, 07632. IAM 15 has purchased Nexium, other than for re-sale (and will purchase generic Nexium other than for re-sale once it becomes available), at supra-competitive prices during the Class Period, and has thereby been injured.

22. Michigan Regional Council of Carpenters Employee Benefits Fund (the "Fund") is a Taft-Hartley fund located in Troy, Michigan that provides health and welfare benefits to union membership. The Fund has purchased Nexium, other than for re-sale (and will purchase generic Nexium other than for re-sale once it becomes available), at supra-competitive prices during the Class Period, and has thereby been injured.

23. A.F. of L. – A.G.C. Building Trades Welfare Plan (the "A.F.L. Plan") is a self-insured health and welfare benefit plan with its principal place of business in Mobile, Alabama. The A.F.L. Plan has purchased Nexium, other than for re-sale (and will purchase generic Nexium

other than for re-sale once it becomes available), at supra-competitive prices during the Class Period, and has thereby been injured.

B. Defendants

24. Defendant AstraZeneca AB is a company organized and existing under the laws of Sweden, having its principal place of business in Sodertalje, Sweden.

25. Defendant Aktiebolaget Hassle is a company organized and existing under the laws of Sweden, having its principal place of business in Molndal, Sweden.

26. Defendant AstraZeneca LP is a limited partnership organized under the laws of Delaware, having its principal place of business in Wilmington, Delaware. AstraZeneca LP holds an approved New Drug Application from the FDA for a delayed-release esomeprazole magnesium formulation that it sells throughout the United States under the brand name Nexium.

27. Defendant Ranbaxy Pharmaceuticals, Inc. is a company organized and existing under the laws of Florida, with its principal place of business at 9431 Florida Mining Blvd. East, Jacksonville, Florida. Ranbaxy Pharmaceuticals, Inc. is a wholly-owned subsidiary of Ranbaxy Laboratories Limited.

28. Defendant Ranbaxy Laboratories Limited is a public limited liability company organized and existing under the laws of India, with a principal place of business located at Plot 90, Sector 32, Gurgaon-122001 (Haryana), India.

29. Defendant Ranbaxy, Inc. is a Delaware corporation, having a place of business at 600 College Road East, Suite 2100, Princeton, New Jersey.

30. Defendants Ranbaxy Pharmaceuticals, Inc., Ranbaxy Laboratories Limited, and Ranbaxy, Inc. are engaged in the worldwide marketing, production and distribution of generic pharmaceutical products.

31. Defendant Teva Pharmaceutical Industries, Ltd. is an Israeli corporation having its principal place of business at 5 Basel St, P.O. Box. 3190, Petach Tkva 49131, Israel.

32. Defendant Teva Pharmaceuticals USA, Inc. is a Delaware corporation, having a principal place of business at 1090 Horsham Road, P.O. Box 1090, North Wales, Pennsylvania.

33. Defendants Teva Pharmaceutical Industries, Ltd. and Teva Pharmaceuticals USA, Inc. are the largest generic manufacturer of pharmaceuticals in the world.

34. Defendant Dr. Reddy's Laboratories, Ltd. is an Indian pharmaceutical company with its principal place of business at Door No 8-2-337, Road No 3, Banjara Hills, Hyderabad – 500034, Andhra Pradesh, India.

35. Defendant Dr. Reddy's Laboratories, Inc. is a New Jersey corporation with its principal place of business at 200 Somerset Corp. Blvd., Bridgewater, New Jersey. On information and belief, Dr. Reddy's Laboratories, Inc. is a wholly-owned subsidiary of Dr. Reddy's Laboratories, Ltd.

36. All of Defendants' actions described in this Complaint are part of, and in furtherance of, the unlawful conduct alleged herein, and were authorized, ordered, and/or done by Defendants' various officers, agents, employees, or other representatives while actively engaged in the management of Defendants' affairs (or that of their predecessors-in-interest) within the course and scope of their duties and employment, and/or with the actual, apparent, and/or ostensible authority of Defendants.

JURISDICTION AND VENUE

37. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332(d) because this is a class action in which the aggregate amount in controversy exceeds $5,000,000 and at least one member of the putative class is a citizen of a state different from that of one of the Defendants.

38. This Court also has jurisdiction over this matter pursuant to 15 U.S.C. § 26 and 28 U.S.C. §§ 1331 and 1337 in that Plaintiffs bring claims under Section 16 of the Clayton Act, 15 U.S.C. § 26, for injunctive and equitable relief to remedy Defendants' violations of Sections 1 and 2 of the Sherman Antitrust Act, 15 U.S. C. §§ 1 and 2. The Court has supplemental jurisdiction over Plaintiffs' pendent state law claims pursuant to 28 U.S.C. § 1367.

39. Venue is appropriate within this district under Section 12 of the Clayton Act, 15 U.S.C. § 22, and 28 U.S.C. §1391(b) and (c), because Defendants transact business within this district and the interstate trade and commerce, hereinafter described, is carried out, in substantial part, in this district.

I. REGULATORY BACKGROUND

A. The Regulatory Structure for Approval of Generic Drugs and the Substitution of Generic Drugs for Brand Name Drugs

40. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), manufacturers that create a new drug product must obtain the approval of the FDA to sell the new drug by filing a New Drug Application ("NDA"). 21 U.S.C. §§ 301-392. An NDA must include submission of specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents. 21 U.S.C. § 355(a), (b).

41. When the FDA approves a brand name manufacturer's NDA, the brand manufacturer may list in the Orange Book any patents that the brand manufacturer believes could reasonably be asserted against a generic manufacturer that makes, uses, or sells a generic version of the brand name drug prior to the expiration of the listed patents. Patents issued after NDA approval may be listed in the Orange Book within thirty days of issuance. 21 U.S.C. §§ 355(b)(1) & (c)(2).

42. The FDA relies completely on the brand name manufacturer's truthfulness about patent validity and applicability, as it does not have the resources or authority to verify the manufacturer's patents for accuracy or trustworthiness. In listing patents in the Orange Book, the FDA merely performs a ministerial act.

1. The Hatch-Waxman Amendments

43. The Hatch-Waxman Amendments, enacted in 1984, simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file lengthy and costly NDAs. *See* Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984). A generic manufacturer seeking approval to sell a generic version of a brand name drug may instead file an ANDA. An ANDA relies on the scientific findings of safety and effectiveness included in the brand name drug manufacturer's original NDA, and must further show that the generic drug contains the same active ingredient(s), dosage form, route of administration, and strength as the brand name drug, and is absorbed at the same rate and to the same extent as the brand drug—that is, that the generic drug is pharmaceutically equivalent and bioequivalent (together, "therapeutically equivalent") to the brand name drug. The FDA assigns generic drugs that are therapeutically equivalent to their brand-name counterpart an "AB" rating.

44. The FDCA and Hatch-Waxman Amendments operate on the presumption that bioequivalent drug products containing identical amounts of the same active ingredients, having the same route of administration and dosage form, and meeting applicable standards of strength, quality, purity and identity, are therapeutically equivalent and may be substituted for one another. Bioequivalence demonstrates that the active ingredient of the proposed generic drug would be present in the blood of a patient to the same extent and for the same amount of time as the branded counterpart. 21 U.S.C. § 355(j)(8)(B).

45. Congress enacted the Hatch-Waxman Amendments to expedite the entry of legitimate (non-infringing) generic competitors, thereby reducing healthcare expenses nationwide. Congress also sought to protect pharmaceutical companies' incentives to create new and innovative products.

46. The Hatch-Waxman Amendments achieved both goals, advancing substantially the rate of generic product launches, and ushering in an era of historic high profit margins for brand name pharmaceutical companies. In 1983, before the Hatch-Waxman Amendments, only 35% of the top-selling drugs with expired patents had generic alternatives; by 1998, nearly all did. In 1984, prescription drug revenue for branded and generic drugs totaled $21.6 billion, with generic drugs accounting for 18.6% of prescriptions. By 2009, total prescription drug revenue had soared to $300 billion, with generic drugs accounting for 75% of prescriptions.

2. Paragraph IV Certifications

47. To obtain FDA approval of an ANDA, a generic manufacturer must certify that the generic drug addressed in its ANDA will not infringe any patents listed in the Orange Book. Under the Hatch-Waxman Amendments, a generic manufacturer's ANDA must contain one of four certifications:

i. that no patent for the brand name drug has been filed with the FDA (a "Paragraph I certification");

ii. that the patent for the brand name drug has expired (a "Paragraph II certification");

iii. that the patent for the brand name drug will expire on a particular date and the generic company does not seek to market its generic product before that date (a "Paragraph III certification"); or

iv. that the patent for the brand name drug is invalid or will not be infringed by the generic manufacturer's proposed product (a "Paragraph IV certification").

48. If a generic manufacturer files a Paragraph IV certification, a brand name manufacturer has the ability to delay FDA approval of the generic's ANDA simply by suing the ANDA applicant for patent infringement. If the brand name manufacturer initiates a patent infringement action against the generic filer within forty-five days of receiving notification of the Paragraph IV certification ("Paragraph IV Litigation"), the FDA will not grant final approval to the ANDA until the earlier of (a) the passage of thirty months, or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. Until one of those conditions occurs, the FDA may grant "tentative approval," but cannot authorize the generic manufacturer to go to market with its product. FDA may grant an ANDA tentative approval when it determines that the ANDA would otherwise be ready for final approval but for the 30-month stay.

49. As an incentive to spur generic companies to seek approval of generic alternatives to branded drugs, the first generic manufacturer to file an ANDA containing a Paragraph IV certification typically gets a period of protection from competition from other generic versions of the drug. For Paragraph IV certifications made after December 2003, the first generic applicant receives 180 days of market exclusivity (unless some forfeiture event, like that discussed below, occurs). This means that the first approved generic is the only available generic for at least six months.

50. Brand name manufacturers can "game the system" by listing patents in the Orange Book (even if such patents are not eligible for listing) and suing any generic competitor that files an ANDA with a Paragraph IV certification (even if the competitor's product does not actually infringe the listed patents) in order to delay final FDA approval of an ANDA for up to 30 months. That brand name manufacturers often sue generics under Hatch-Waxman simply to

delay generic competition—as opposed to enforcing valid patents that are actually infringed by the generic—is demonstrated by the fact that generic firms have prevailed in Paragraph IV Litigation, by obtaining a judgment of invalidity or non-infringement or by the patent holder's voluntary dismissal, in cases involving 73% of the cases studied.

51. The first generic applicant can help the brand manufacturer "game the system" by delaying not only its own market entry, but also the market entry of all other generic manufacturers. The first generic applicant, by agreeing not to begin marketing its generic drug, thereby delays the start of the 180-day period of generic market exclusivity, a tactic called exclusivity "parking." This tactic creates a "bottleneck" because later generic applicants cannot launch until the first generic applicant's 180-day exclusivity has elapsed or is forfeited.

3. Forfeiture Provisions Under the MMA

52. On December 8, 2003, Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA") in order to make it more difficult for brand and generic pharmaceutical companies to conspire in order to delay the start of the first-filer's 180-day period of generic market exclusivity. The MMA outlines a number of conditions under which an ANDA applicant forfeits its eligibility for 180-day exclusivity, making way for other ANDA filers to launch their generic products.

53. Under the "failure to market" provision, a first ANDA applicant will forfeit 180-day exclusivity if it fails to market its generic drug by the later of: (a) the earlier of the date that is (i) 75 days after receiving final FDA approval; or (ii) 30 months after the date it submitted its ANDA; or (b) the date that is 75 days after the date as of which, as to each of the patents that qualified the first applicant for exclusivity (*i.e.*, as to each patent for which the first applicant submitted a Paragraph IV certification), at least one of the following has occurred: (i) a final decision of invalidity or non-infringement; (ii) a settlement order entering final judgment that

includes a finding that the patent is invalid or not infringed; or (iii) the NDA holder delists the patent from the FDA Orange Book.

54. Brand name manufacturers and first-filing generics are able to structure their settlements in order to intentionally skirt the failure-to-market provisions and keep the 180-day exclusivity bottleneck in place by, for example, settling their litigation before a final judgment of invalidity or non-infringement can be entered with respect to each of the patents for which the first applicant submitted a Paragraph IV certification or seeking a consent judgment settling the litigation that does not include a finding that all of the patents for which the first applicant submitted a Paragraph IV certification were invalid or not infringed. When that happens, in order to trigger forfeiture and gain access to the market, subsequent ANDA applicants are forced to obtain a judgment that all patents for which the first filing generic company filed Paragraph IV certifications are invalid or not infringed. This may require the subsequent ANDA applicant to initiate a declaratory judgment action over patents that the brand company did not assert against it in a Paragraph IV Litigation.

B. No-Authorized Generic Agreements

55. An authorized generic drug is chemically identical to the brand name drug, but marketed and sold as a generic product under the branded product's original NDA. Brand name companies frequently launch authorized generics to compete with first-filing generics and preserver their profits during the 180-day exclusivity period. Competition between the authorized generic and the first-filing generic during the 180-day exclusivity period lowers prices for consumers and other drug purchasers.

56. Authorized generics have a significant negative impact on a first-filing generic's revenues. In an August 2011 report issued by the Federal Trade Commission, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact*, the FTC concluded, after analyzing

documents and empirical data from more than 100 companies, that authorized generics reduce a first-filer's revenues by approximately 50 percent during the 180-day exclusivity period. The negative effects of an authorized generic on the first-filer also continue well after exclusivity expires, as the FTC found that revenues of the first-filer generic in the 30 months following exclusivity are between 53 percent and 62 percent lower when facing an authorized generic. The FTC also concluded that wholesale and retail prices decrease when the first-filer competes with an authorized generic.

57. According to the FTC, because freedom from an authorized generic is extremely valuable to first-filing generics, promises not to compete with generic entrants by marketing an authorized generic are a form of consideration paid by brand manufacturers to generics in exchange for the generics' agreement to delay market entry. Although a brand company will lose some product revenue and profits from agreeing not to market an authorized generic, it makes far more in branded profits and sales by paying a generic to delay market entry with the no-authorized generic agreement. Thus, the brand and generic companies reap greater revenues and profits under no-authorized generic agreements, but consumers and other purchasers are forced to pay higher prices resulting from the delay in generic competition bought by the no-authorized generic agreement and the lack of competition between the first-filing generic and the authorized generic during the 180-day exclusivity period (once the first-filing generic finally launches its generic product).

58. No-authorized generic agreements come in many forms. They are commonly structured as an "exclusive license" under which the brand company agrees to grant the first-filing generic exclusivity to market its generic product during the 180-day exclusivity period.

59. For a generic company which is first to file an ANDA for a $3 billion a year branded product like Nexium, the difference between selling the only generic product and having to compete with an authorized generic can amount to hundreds of millions of dollars or more. These economic realities, as confirmed and presented by the FTC in its 2011 authorized generic report, are well known in the pharmaceutical industry.

C. The Benefits of Generic Drugs

60. Typically, AB-rated generics cost much less than their branded counterparts. Because of the price differentials, and other institutional features of the pharmaceutical industry, generic versions are liberally and substantially substituted by pharmacists who are presented with a prescription for the brand-name counterpart. Since passage of the Hatch-Waxman Amendments, every State has adopted substitution laws that either require or permit pharmacies to substitute AB-rated generic equivalents for branded prescriptions (unless the prescribing physician has specifically ordered otherwise by writing on the prescription "dispense as written").

61. There is an incentive to choose the less expensive generic equivalent in every link in the prescription drug chain. As a result of federal reimbursement rules and the industry pricing structure, pharmacies typically earn a higher markup on generics. Private health insurers similarly offer direct incentives to pharmacies to substitute cheaper generic products for more expensive branded ones. Health insurers are contractually obligated to pay for the bulk of their members' prescriptions, whether filled with branded or generic drugs, so they offer their members lower copays for generic drugs in order to encourage the use of generics. Members also face the threat of increased health insurance premiums if branded prescription drug costs continue to rise.

62. As more generic equivalents compete with each other, prices decline even further as a result of competition among the generic manufacturers, and pharmacy substitution and thus the loss of sales volume by the brand name drug to the corresponding generic accelerates. And the speed with which generic drugs take over the market is increasing: in a sample of drugs losing patent protection between 1991 and 1993, generics held, on average, a 44% market share after one year; by 2008, generic versions could capture as much as 86% to 97% of the market within the first month of availability. Generic competition enables all members of the proposed Class to: (a) purchase generic versions of the drug at substantially lower prices; and/or (b) purchase the brand name drug at a reduced price.

63. However, until a generic version of the brand name drug enters the market, there is no bioequivalent generic drug to substitute for and compete with the brand name drug, and therefore the brand name manufacturer can continue to charge supracompetitive prices profitably without losing all or a substantial portion of its brand name sales. As a result, brand-name drug manufacturers, who are well aware of generics' rapid erosion of their brand name sales, have a strong incentive to delay the introduction of generic competition into the market, including by using tactics such as the Agreements alleged above and below.

II. FACTUAL ALLEGATIONS

A. Defendants' Unlawful Conduct

1. AstraZeneca Files Paragraph IV Litigation Against the Generic Defendants

64. Nexium is a prescription proton pump inhibitor ("PPI") used to treat heartburn and related conditions. The active ingredient in Nexium is esomeprazole magnesium. Its pharmacological profile, and thus its side effect and efficacy profile, is different than other PPIs, H2 blockers and non-prescription antacids that are used to treat the same or similar conditions. Those other drugs are not AB-rated to Nexium, cannot be automatically substituted for Nexium

by pharmacists, do not exhibit substantial cross-price elasticity of demand with respect to Nexium, and thus are not economic substitutes for, nor reasonably interchangeable with, Nexium.

65. On December 3, 1999, AstraZeneca submitted NDA 21-153 seeking FDA approval to market esomeprazole magnesium delayed-release capsules in 20 mg and 40 mg strengths under the brand name Nexium for the healing of erosive esophagitis, maintenance of healing of erosive esophagitis, and treatment of symptomatic gastroesophageal reflux disease. The FDA approved AstraZeneca's NDA for Nexium on February 20, 2001.

66. In connection with its Nexium NDA, AstraZeneca listed fourteen patents in the FDA Orange Book as covering Nexium or a method of using Nexium (the "Nexium patents"). Although the Nexium patents purport to cover, among other things, compounds and pharmaceutical compositions comprised of magnesium salts of esomeprazole, and methods of using those compounds and compositions, there existed a substantial risk that the patents would be invalidated upon a challenge from generic manufacturers.

67. Among other reasons, the Nexium patents are inherently weak because the esomeprazole "invention" described in the various Nexium patents is *prima facie* obvious in light of the prior art, including, but not limited to, AstraZeneca's prior PPI drug, Prilosec.

68. The active ingredient in Prilosec is omeprazole. Omeprazole is a "racemate," which is a substance consisting of equal parts of two different isomers of the same molecule. The different isomers, known as "enantiomers," are non-superimposable mirror images of one another but are otherwise identical. Human hands are commonly used to illustrate this principle. A person's left hand and right hand are non-superimposable mirror images of each other. Pairs of enantiomers share many chemical and physical properties, though they may exhibit very

different biologic activity. For example, it is commonly known that one enantiomer of the pair will be more biologically active than the other.

69. A 20 mg dose of the racemate omeprazole contains 10 mg of the left-handed or "S" (for *sinister*, the Latin word for "left-handed") enantiomer and 10 mg of the right-handed or "R" enantiomer. Nexium, which contains esomeprazole, the S-enantiomer of omeprazole, is simply Prilosec without the less active R-enantiomer.

70. Under well-settled patent law principles, in the case of chemical compounds where the prior art is close enough to the claimed invention to give one skilled in the relevant chemical art the motivation to make close relatives of the prior art compound, like enantiomers, there arises a presumption of obviousness, *i.e.*, a *prima facie* case of obviousness. Accordingly, enantiomers like Nexium are frequently assumed to be *prima facie* obvious in light of their racemates, shifting the burden to the patentee to establish validity.

71. AstraZeneca faced substantial risk that its Nexium patents would be invalidated through patent litigation. In fact, the European Patent Office ruled, first in 2006 and then again in 2011, in connection with opposition proceedings brought by generic manufacturers, including at least Generic Defendant Teva, that two European Nexium patents—which are similar to U.S. Nexium patents—were not just presumed to be invalid, but actually were invalid and thus revoked for failing to satisfy the "inventive step" requirement, which is analogous to obviousness under U.S. patent law.

72. Because the Nexium patents are particularly susceptible to attack on validity grounds, generic companies were eager to apply for FDA approval to market generic versions of Nexium prior to the expiration of the Nexium patents.

73. On or about October 14, 2005, Generic Defendant Ranbaxy notified AstraZeneca that it had filed ANDA No. 77-830, seeking to market generic versions of Nexium containing 20 mg and 40 mg of esomeprazole magnesium in delayed-release capsules. Ranbaxy's notice letter included a Paragraph IV certification that the commercial manufacture, use and/or sale of its generic Nexium product would not infringe any valid claim of any patent that expired after October 2007 listed in the FDA Orange Book as covering Nexium or a method of using Nexium.

74. On November 21, 2005, AstraZeneca filed suit in the United States District Court for the District of New Jersey pursuant to Hatch-Waxman (the "Ranbaxy Litigation"), alleging that Ranbaxy's generic Nexium product would infringe six patents, five of which were Orange Book-listed: U.S. Patent No. 5,714,504 (the "'504 patent"); U.S. Patent No. 5,877,192 (the "'192 patent); U.S. Patent No. 6,875,872 (the "'872 patent"); U.S. Patent No. 6,428,810 (the "'810 patent"); U.S. Patent No. 6,369,085 (the "'085 patent"); and U.S. Patent No. 5,948,789 (the "'789 patent"). Each of the patents was weak and likely to be adjudicated invalid, unenforceable or non-infringed during the Ranbaxy Litigation.

75. AstraZeneca never brought litigation against Ranbaxy on the other nine Nexium patents it had listed in the Orange Book: U.S. Patent No. 4,786,505 (the "'505 patent"); U.S. Patent No. 4,853,230 (the "'230 patent); U.S. Patent No. 4,738,974 (the "'974 patent"); U.S. Patent No. 5,690,960 (the "'960 patent"); U.S. Patent No. 5,900,424 (the "'424 patent"); U.S. Patent No. 7,411,070 (the "'070 patent"); U.S. Patent No. 6,147,103 (the "'103 patent"); U.S. Patent No. 6,191,148 (the "'148 patent"); and U.S. Patent No. 6,166,213 (the "'213 patent"). These nine patents would not have barred Ranbaxy's market entry in April 2008.

76. There was substantial uncertainty that AstraZeneca would prevail in asserting infringement claims against Ranbaxy. The Nexium patents, absent the unlawful Agreement,

would not have barred Ranbaxy's entry in the market with a generic Nexium product in April 2008.

77. On or about January 26, 2006, Generic Defendant Teva notified AstraZeneca that it had filed ANDA No. 78-003, seeking to market generic versions of Nexium containing 20 mg and 40 mg of esomeprazole magnesium in delayed-release capsules. Teva's notice letter included a Paragraph IV certification that the commercial manufacture, use and/or sale of its generic product would not infringe any valid claim of any patent listed in the FDA Orange Book as covering Nexium or a method of using Nexium.

78. On March 8, 2006, AstraZeneca filed suit against Teva in the United States District Court for the District of New Jersey pursuant to Hatch-Waxman (the "Teva Litigation"), alleging that Teva's generic Nexium product would infringe five of the patents listed in the Orange Book for Nexium: the '504; '192; '872; '810; and '085 patents. Subsequently, AstraZeneca amended its complaint by dropping its allegation that Teva infringed the '810 patent and adding an allegation that Teva infringed the '789 patent and U.S. Patent No. 7,411,070 (the "'070 patent"). Each of the patents was weak and likely to be adjudicated invalid, unenforceable or non-infringed during the Teva Litigation.

79. AstraZeneca never brought litigation against Teva on the other eight Nexium patents it had listed in the Orange Book: the '505 patent; the '230 patent; the '974 patent; the '960 patent; the '424 patent; the '103 patent; the '148 patent; and the '213 patent. These eight patents would not have barred Teva's market entry in late 2008.

80. There was substantial uncertainty that AstraZeneca would prevail in asserting infringement claims against Teva. The Nexium patents, absent the unlawful Agreement, would not have barred Teva's early entry in the market with a generic Nexium product.

81. On August 17, 2006, Generic Defendant Dr. Reddy's notified AstraZeneca that it had filed ANDA No. 78-279, seeking to market generic versions of Nexium containing 20 mg and 40 mg of esomeprazole magnesium in delayed-release capsules. Dr. Reddy's notice letter included a Paragraph IV certification that the commercial manufacture, use and/or sale of its generic product would not infringe any valid claim of seven of the Orange Book-listed patents, including the '085 and the '810 patents. On December 4, 2007, Dr. Reddy's amended its ANDA to assert that its proposed generic Nexium product would not infringe the '504, '192 or '872 patents, or that those patents were invalid.

82. On January 17, 2008, AstraZeneca filed suit in the United States District Court for the District of New Jersey pursuant to Hatch-Waxman (the "Dr. Reddy's Litigation"), alleging that Dr. Reddy's generic Nexium product would infringe three of the patents listed in the Orange Book for Nexium: the '504; '872; and '085 patents. In reply to Dr. Reddy's answer, AstraZeneca also asserted that Dr. Reddy's proposed generic Nexium product would infringe the '192 patent. These patents were weak and likely to be adjudicated invalid, unenforceable or non-infringed during the Dr. Reddy's Litigation.

83. AstraZeneca later dropped its claim that Dr. Reddy's infringed the '085 patent. The parties entered a Consent Agreement pursuant to which the court entered a final decision that Dr. Reddy's generic Nexium product did not infringe any claim of the '085 patent.

84. On May 19, 2008, Dr. Reddy's filed a complaint seeking a declaratory judgment that its generic Nexium product would not infringe the '960 patent; the '424 patent; the '103 patent; the '148 patent; the '213 patent; or the '810 patent. In its answer, AstraZeneca admitted that Dr. Reddy's proposed generic Nexium product would not infringe the '148 patent or the '810 patent.

85. AstraZeneca never brought litigation against Dr. Reddy's on the other ten Nexium patents it had listed in the Orange Book: the '505 patent; the '230 patent; the '974 patent; the '960 patent; the '424 patent; the '103 patent; the '148 patent; the '213 patent; the '810 patent; and the '070 patent. These ten patents would not have barred Dr. Reddy's market entry.

86. There was substantial uncertainty that AstraZeneca would prevail in asserting infringement claims against Dr. Reddy's. The Nexium patents, absent the unlawful Agreement, would not have barred Dr. Reddy's early entry in the market with a generic Nexium product.

87. AstraZeneca's actions against the Generic Defendants were consolidated, and the Generic Defendants conducted discovery supporting a host of defenses focusing on: (1) the enforceability of the Nexium patents; (2) the validity of the Nexium patents' claims; and (3) the strength of AstraZeneca's infringement allegations. AstraZeneca and the Generic Defendants entered Exclusion Payment Agreements before any dispositive motions relating to the Generic Defendants' substantive challenges to the patents were decided.

88. To prevent generic entry using just its patents (rather than pay-offs), AstraZeneca would have had to show that each of the generic Nexium products infringed its patents and defeat each of the generic companies' invalidity arguments. AstraZeneca instead decided to protect its monopoly by paying all of the Generic Defendants to withdraw their challenges to the validity and enforceability of its patents and delay their introduction of generic Nexium. And that is precisely what it has done, in concert with the Generic Defendants.

89. As described in detail below, the Exclusion Payment Agreements were part of an overarching scheme consisting of, *inter alia*: (a) unlawful agreements to delay generic entry between AstraZeneca and each individual Generic Defendant; and (b) an agreement, engineered by AstraZeneca, not to compete with, between and among AstraZeneca and the Generic

Defendants. The Agreements each contain the same agreed-upon generic entry date, as well as a provision that allows a settling Generic Defendant to accelerate market entry if another generic competitor successfully challenged the Nexium patents.

2. AstraZeneca and Ranbaxy Enter an Exclusion Payment Agreement

90. On or about April 14, 2008, shortly after discovery ended and before the court could issue any substantive rulings, AstraZeneca and Ranbaxy entered into the AstraZeneca/Ranbaxy Exclusion Payment Agreement. Pursuant to that Agreement, AstraZeneca ended its litigation against first-filer Ranbaxy, and a consent judgment was entered by the court on the exact same day that the 30-month stay of FDA approval of Ranbaxy's generic Nexium product expired.

91. Under the Exclusion Payment Agreement, Ranbaxy agreed to: (a) admit that the '504, '192, '789, '085, '810 and '872 patents were enforceable and valid; (b) admit that its generic Nexium products would infringe the '504, '192, '789 and '872 patents (but not the '810 or '085 patents); and (c) delay launching its generic Nexium product until May 27, 2014 unless otherwise specifically authorized by the Agreement (which included earlier entry by another generic).

92. As the *quid pro quo* for Ranbaxy's agreement to drop its challenge to the Nexium patents listed above and to delay entry of its generic Nexium product until May 27, 2014, AstraZeneca agreed, pursuant to the Agreement, to pay Ranbaxy over a billion dollars.

93. Shortly after AstraZeneca and Ranbaxy entered the Agreement, Ranbaxy's Chief Executive Officer, Malvinder Singh, boasted that the Agreement would give Ranbaxy as much as *$1.5 billion* in revenue between the date of the Agreement and the end of its 180-day marketing exclusivity in 2014. Singh characterized the Agreement as "the biggest and most

comprehensive settlement to date by any generic company globally." Upon information and belief, AstraZeneca has already paid Ranbaxy millions of dollars under their Agreement.

94. However, according to a press statement published two days after the Agreement, the bulk of Ranbaxy's revenues under the Agreement will not accrue until 2014—when Ranbaxy is able to launch its generic Nexium product for 180 days free of competition from any other generic Nexium product, including an authorized generic sold by AstraZeneca. As part of its consideration to induce Ranbaxy's agreement to delay its market entry until May 27, 2014 AstraZeneca agreed, pursuant to an exclusive license, not to launch an authorized generic during Ranbaxy's 180-day exclusivity period. This no-authorized generic agreement constituted a substantial payment to Ranbaxy—nearly one billion dollars.

95. Although AstraZeneca's payments to Ranbaxy under the Agreement are characterized as an exclusive license and payments for Ranbaxy's performance of manufacturing and distribution services for AstraZeneca, those characterizations are pretextual. In fact, the payments from AstraZeneca to Ranbaxy were for Ranbaxy's agreement to delay generic competition to Nexium for over six years. Absent Ranbaxy's agreement to delay entry into the market with generic Nexium, AstraZeneca would not have made the no authorized generic agreement or agreed to designate Ranbaxy as a supplier of Nexium and Nexium API, or as the authorized generic distributor for Plendil or Prilosec, and/or would not have agreed to the price and/or other terms that it did under those provisions of the Agreement. AstraZeneca paid Ranbaxy for delayed market entry of generic Nexium.

3. AstraZeneca Enters Exclusion Payment Agreements with Teva and Dr. Reddy's to Strengthen the Bottleneck Created by the AstraZeneca/Ranbaxy Exclusion Payment Agreement

96. On April 30, 2008, shortly after AstraZeneca and Rabaxy entered their Agreement, Generic Defendant Teva filed a declaratory judgment action against AstraZeneca

seeking a ruling of invalidity and non-infringement regarding the remaining Orange Book-listed patents that AstraZeneca did not sue Teva for infringing in connection with Teva's generic Nexium ANDA. Teva filed its declaratory judgment action in an attempt to obtain a favorable judgment regarding all Orange Book-listed Nexium patents and thus uncork the FDA approval bottleneck caused by AstraZeneca's settlement with first-filer Ranbaxy, which (absent some other forfeiture event) ensures that Ranbaxy will not trigger its 180-day marketing exclusivity until May 27, 2014. Dr. Reddy's followed in May 2008 with its own declaratory judgment action seeking a ruling of non-infringement with respect to the unasserted Orange Book-listed patents.

97. In response to AstraZeneca's motion to dismiss its declaratory judgment action for lack of jurisdiction, Teva accused AstraZeneca of gaming the system "to take advantage of what [Teva] contends is an *invalid and illegitimate patent monopoly*." According to Teva, as a result of the Exclusion Payment Agreement between AstraZeneca and Ranbaxy, if it could not "challenge the patents in suit, the patents will represent a six-year barrier to anyone entering the market, regardless of whether they are valid or would be infringed. In those circumstances, [Teva] would be precluded from marketing its product and the public would not have access to lower-priced esomeprazole *even though no legitimate patent rights protect defendants' monopoly*."

98. The court denied in substantial part AstraZeneca's motion to dismiss the declaratory judgment actions, but granted AstraZeneca's motion to stay the declaratory action pending resolution of the main infringement action. Although on reconsideration the court permitted the declaratory judgment actions to proceed, AstraZeneca succeeded in delaying for

approximately six months Teva's and Dr. Reddy's efforts to obtain a court judgment that could allow generic market entry before May 27, 2014.

a. AstraZeneca and Teva Enter an Exclusion Payment Agreement

99. In the interim, however, Teva and AstraZeneca entered into the AstraZeneca/Teva Agreement. Although claim construction was briefed during the summer of 2009, AstraZeneca and Teva, pursuant to their Agreement, repeatedly asked the court to postpone construing the contested claims of the Nexium patents. The protracted delay meant that the court had issued no substantive rulings as of January 7, 2010. On or about that date, AstraZeneca and Teva entered into the AstraZeneca/Teva Exclusion Payment Agreement, which ended the litigation between AstraZeneca and Teva.

100. Under the Exclusion Payment Agreement, Teva agreed to: (a) admit that all patents then listed in the Orange Book as covering Nexium "are all enforceable and valid with respect to certain products;" (b) admit that its generic Nexium product would infringe the '504, '192, '789, '085, '872 and '070 patents; and (c) delay launching its generic Nexium until May 27, 2014 unless otherwise specifically authorized by the Agreement (which included earlier entry by another generic).

101. As the *quid pro quo* for Teva's agreement to drop its challenge to the Nexium patents and to delay entry of its generic Nexium product until May 27, 2014, AstraZeneca agreed, pursuant to the Agreement, to pay Teva. That payment came in the form of AstraZeneca's forgiveness of Teva from a contingent liability.

102. Teva had an enormous contingent liability to AstraZeneca. On September 9, 2004, Teva had commenced an "at risk" launch of generic Prilosec, which was manufactured by its marketing partner Impax. In 2008, the Federal Circuit affirmed the district court's ruling that

the Prilosec patents were valid and infringed by Impax's generic Prilosec product. Because Teva and Impax shared the risk with respect to any damages associated with the sale of the generic Prilosec product, there was substantial risk that Teva would owe AstraZeneca potentially massive infringement damages resulting from years of infringing generic Prilosec sales. As part of and simultaneously with their Exclusion Payment Agreement, Teva and AstraZeneca agreed that Teva would pay only an amount that AstraZeneca characterized as not financially material to account for its past infringing Prilosec sales. By forgiving the substantial part of Teva's contingent liability to it with respect to a different drug, AstraZeneca paid Teva.

103. The true purpose and effect of AstraZeneca's payment to Teva was to delay generic competition to Nexium until May 27, 2014. Absent Teva's agreement to delay entry into the market with generic Nexium, AstraZeneca would not have forgiven Teva substantially all of the contingent liability and/or would not have done so on the terms that it did. AstraZeneca paid Teva for delayed market entry of generic Nexium.

b. AstraZeneca and Dr. Reddy's Enter an Exclusion Payment Agreement

104. On or about January 28, 2011, before the court could issue any dispositive decision regarding the validity or infringement of the Nexium patents, AstraZeneca and Dr. Reddy's entered the AstraZeneca/Dr. Reddy's Exclusion Payment Agreement, which ended the litigation between AstraZeneca and Dr. Reddy's and delayed entry of Dr. Reddy's generic Nexium products until May 27, 2014 unless specifically authorized by the Agreement (which included earlier entry by another generic).

105. As the *quid pro quo* for Dr. Reddy's agreement to drop its challenge to the Nexium patents and to stay out of the Nexium market until May 27, 2014, AstraZeneca agreed to pay Dr. Reddy's by forgiving Dr. Reddy's from an outstanding contingent liability.

106. Dr. Reddy's had a substantial contingent liability to AstraZeneca. Dr. Reddy's had launched its generic version of AstraZeneca's Accolate product "at risk" in November 2010, following a summary judgment opinion in Dr. Reddy's favor that AstraZeneca had appealed at the time of the Agreement. By agreeing, as part of and simultaneously with the Agreement, to drop its appeal and thereby remove the risk that Dr. Reddy's would have to pay substantial damages with respect to its generic Accolate sales, AstraZeneca paid Dr. Reddy's under the Agreement.

107. The true purpose and effect of AstraZeneca's payment to Dr. Reddy's was to delay generic competition to Nexium until May 27, 2014. Absent Dr. Reddy's agreement to delay entry into the market with generic Nexium, AstraZeneca would not have forgiven Dr. Reddy's of the contingent liability against it and/or would not have done so on the terms that it did. AstraZeneca paid Dr. Reddy's for delayed market entry of generic Nexium.

108. By paying Teva and Dr. Reddy's not to market their generic Nexium products before May 27, 2014, and by doing so before the court could rule on the validity or infringement of the Nexium patents, AstraZeneca ensured that the second and third ANDA-filers could not dislodge the FDA approval bottleneck created by its Agreement with first-filer Ranbaxy.

B. Anticompetitive Purpose and Effect of the Agreements

109. AstraZeneca's payments to the Generic Defendants under the xEclusion Payment Agreements demonstrate Defendants' anticompetitive purpose and intent.

110. The Agreements harmed Plaintiffs and the Class by depriving them of a market in which manufacturers and distributors of generic drugs make their decisions about challenging patents, defending appeals and entering markets free from the influence of payments from brand manufacturers. Contrary to the purpose of the Hatch-Waxman Act, the Agreements have enabled AstraZeneca and the Generic Defendants to: (a) preclude the entry of less expensive

generic versions of Nexium products in the United States; (b) fix, raise, maintain or stabilize the price of Nexium products; (c) permit AstraZeneca to maintain a monopoly in the U.S. market for Nexium products; and (d) allocate 100% of the U.S. market for delayed-release esomeprazole magnesium to AstraZeneca.

111. But for the Agreements: (i) Ranbaxy (or another ANDA filer) would have received final marketing approval from the FDA on or about April 14, 2008 and Ranbaxy or another ANDA filer would have begun selling AB-rated generic versions of Nexium shortly thereafter; and (ii) an increasingly competitive market for delayed-release esomeprazole magnesium would have emerged following the expiration of Ranbaxy's 180-day exclusivity period, as additional generic manufacturers entered the market.

112. Defendants' unlawful concerted action has delayed or prevented the sale of generic Nexium in the United States, and unlawfully enabled AstraZeneca to sell Nexium at artificially inflated, supra-competitive prices. But for Defendants' illegal conduct, generic competition to Nexium would have occurred already, because one or more of the Generic Defendants would have already entered with its generic version of Nexium.

III. CLASS ACTION ALLEGATIONS

113. Plaintiffs bring this action on behalf of themselves and, under Fed. R. Civ. P. 23(a), (b)(2) and (b)(3), as representatives of an End-Payor Class defined as follows:

> All persons or entities who purchased and/or paid for some or all of the purchase price for Nexium and/or its AB-rated generic equivalents in the States specified below and the District of Columbia and Puerto Rico in any form, for consumption by themselves, their families, or their members, employees, insureds, participants, or beneficiaries (the "Class" or the "End-Payor Class"), other than for resale, during the period April 14, 2008 through and until the anticompetitive effects of Defendants' unlawful conduct cease (the "Class Period"). For purposes of the Class definition, persons or entities "purchased" Nexium or its

generic equivalent if they paid or reimbursed some or all of the purchase price.

114. The following persons or entities are excluded from the proposed End-Payor Class:

a. Defendants and their officers, directors, management, employees, subsidiaries, or affiliates;

b. All governmental entities, except for governmental funded employee benefit plans;

c. All persons or entities who purchased Nexium or its AB-rated generic equivalent for purposes of resale or directly from Defendants or their affiliates;

d. Fully insured health plans (*i.e.*, Plans that purchased insurance from another third-party payor covering 100% of the Plan's reimbursement obligations to its members);

e. Any "flat co-pay" consumers whose purchases were paid in part by a third party payor and whose co-payment was the same regardless of the retail purchase price;

f. Any "brand loyalist" consumers or third-party payors who purchased Nexium and who did not purchase any AB-rated generic equivalent after such generics became available; and

g. The judges in this case and any members of their immediate families.

115. Members of the End-Payor Class are so numerous that joinder is impracticable. Plaintiffs believe that the Class includes hundreds of thousands, if not millions, of consumers, and thousands of third-party payors.

116. Plaintiffs' claims are typical of the claims of the members of the End-Payor Class. Plaintiffs and all members of the End-Payor Class were damaged by the same wrongful conduct of Defendants, *i.e.*, they paid artificially inflated prices for Nexium and were deprived of the benefits of earlier and more robust competition from cheaper generic versions of Nexium as a result of Defendants' wrongful conduct.

117. Plaintiffs will fairly and adequately protect and represent the interests of the End-Payor Class. The interests of the Plaintiffs are coincident with, and not antagonistic to, those of the End-Payor Class.

118. Plaintiffs are represented by counsel with experience in the prosecution of class action antitrust litigation, and with particular experience with class action antitrust litigation involving pharmaceutical products.

119. Questions of law and fact common to the members of the End-Payor Class predominate over questions that may affect only individual Class members because Defendants have acted on grounds generally applicable to the entire End-Payor Class, thereby making overcharge damages with respect to the End-Payor Class as a whole appropriate.

120. Questions of law and fact common to the End-Payor Class include, but are not limited to:

a. whether Defendants conspired to willfully maintain and/or enhance AstraZeneca's monopoly power over Nexium and its generic equivalents;

b. whether Defendants conspired to suppress generic competition to Nexium;

c. whether Defendants entered into an unlawful agreement in restraint of trade;

d. whether, pursuant to the Agreements, the Generic Defendants agreed to delay their entry into the market with generic Nexium;

e. whether, pursuant to the Agreements, AstraZeneca compensated the Generic Defendants;

f. whether AstraZeneca's compensation to the Generic Defendants was for a purpose other than delayed entry of generic Nexium;

g. whether AstraZeneca's compensation to the Generic Defendants was necessary to yield some procompetitive benefit that is cognizable and non-pretextual;

h. whether the Agreements created a bottleneck to generic competition;

i. whether one or more of the Agreements is *per se* illegal, illegal under a "quick look" analysis, or illegal under the rule of reason;

j. whether AstraZeneca possessed monopoly power over Nexium;

k. whether the law requires definition of a relevant market when direct proof of monopoly power is available and, if so, the definition of the relevant market;

l. whether the activities of Defendants as alleged herein have substantially affected interstate commerce;

m. whether, and to what extent, Defendants' conduct caused antitrust injury (*i.e.*, overcharges) to Plaintiffs and the members of the Class; and

n. the quantum of aggregate overcharge damages to the Class.

121. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. Such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities a method for obtaining redress on claims that could not practicably be pursued individually, substantially outweighs potential difficulties in management of this class action.

122. Plaintiffs know of no special difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

IV. INTERSTATE AND INTRASTATE COMMERCE

123. At all material times, AstraZeneca manufactured, promoted, distributed, and sold substantial amounts of Nexium in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States.

124. At all material times, Defendants transmitted funds, as well as contracts, invoices and other forms of business communications and transactions, in a continuous and uninterrupted

flow of commerce across state and national lines in connection with the sale of Nexium and/or AB-rated bioequivalents.

125. In furtherance of their efforts to monopolize and restrain competition in the market for delayed-release esomeprazole magnesium, Defendants employed the United States mails and interstate and international telephone lines, as well as means of interstate and international travel. The activities of Defendants were within the flow of and have substantially affected interstate commerce.

126. Defendants' anticompetitive conduct has substantial intrastate effects in that, *inter alia*, retailers within each state are foreclosed from offering cheaper generic Nexium to end-payors inside each respective state. The complete foreclosure of generic Nexium directly impacts and disrupts commerce for end-payors within each state.

V. MONOPOLY POWER AND MARKET DEFINITION

127. AstraZeneca has monopoly power over delayed-release esomeprazole magnesium because it had the power to raise the price of the drug it sells as Nexium to supracompetitive levels without losing so many sales as to make those supracompetitive prices unprofitable.

128. A small but significant, non-transitory price increase for Nexium by AstraZeneca would not cause such a loss of sales.

129. At competitive levels, Nexium does not exhibit significant, positive cross-elasticity of demand with respect to price with any product other than AB-rated generic versions of Nexium.

130. Because of, among other reasons, its use and varying ability to heal erosive esophagitis, maintain the healing of erosive esophagitis, and treat symptomatic gastroesophageal reflux disease, Nexium is differentiated from all products other than AB-rated generic versions of Nexium.

131. AstraZeneca needed to control only Nexium and its AB-rated generic equivalents, and no other products, in order to maintain the price of Nexium profitably at supracompetitive prices. Only the market entry of a competing, AB-rated generic version of Nexium would render AstraZeneca unable to profitably maintain its supracompetitive prices of Nexium.

132. AstraZeneca also sold Nexium at prices well in excess of marginal costs, and in excess of the competitive price, and enjoyed high profit margins.

133. Defendants have had, and exercised, the power to exclude and restrict competition to Nexium and AB-rated bioequivalents.

134. AstraZeneca, at all relevant times, enjoyed high barriers to entry with respect to competition to the relevant product market due to patent and other regulatory protections and high costs of entry and expansion.

135. To the extent that Plaintiffs are legally required to prove monopoly power circumstantially by first defining a relevant product market, Plaintiffs allege that the relevant market is delayed-release esomeprazole magnesium (*i.e.*, Nexium and its AB-rated generic equivalents). During the period relevant to this case, AstraZeneca has been able to profitably maintain the price of delayed-release esomeprazole magnesium well above competitive levels.

136. The relevant geographic market is the United States and its territories.

137. At all relevant times, AstraZeneca's market share in the relevant market was and remains 100%, implying a substantial amount of monopoly power.

VI. MARKET EFFECTS AND DAMAGES TO THE CLASS

138. Ranbaxy's ANDA was in approvable condition as of February 5, 2008 when it received tentative approval. FDA issues tentative approval only when it determines that an ANDA would otherwise be ready for final approval but for the 30-month stay. Were it not for the AstraZeneca/Ranbaxy Agreement, Ranbaxy would have received final FDA approval on or

about April 14, 2008, the date the 30-month stay of FDA approval expired. Generic Nexium products would have entered the market shortly thereafter.

139. FDA has not given Ranbaxy's generic Nexium ANDA final approval solely because FDA knows that the AstraZeneca/Ranbaxy Exclusion Payment Agreement prevents Ranbaxy from selling generic Nexium until May 27, 2014. By practice, FDA organizes its priorities around "rate limiters," and the AsraZeneca/Ranbaxy Agreement is a rate limiter that has caused FDA to wait to issue formal, written approval to Ranbaxy's ANDA.

140. Defendants' Exclusion Payment Agreements had the purpose and effect of restraining competition unreasonably and injuring competition by protecting Nexium from generic competition. Defendants' actions allowed AstraZeneca to maintain a monopoly and to exclude competition in the market for delayed-release esomeprazole magnesium, to the detriment of Plaintiffs and all other members of the Class.

141. Defendants' Exclusion Payment Agreements have delayed generic competition and unlawfully enabled AstraZeneca to sell Nexium without generic competition. But for Defendants' illegal conduct, one or more generic competitors would have begun marketing AB-rated generic versions of Nexium by April 14, 2008 or shortly thereafter, and AstraZeneca would have simultaneously launched an authorized generic version of Nexium.

142. The generic manufacturers seeking to sell generic Nexium had extensive experience in the pharmaceutical industry, including in obtaining approval for ANDAs and marketing generic pharmaceutical products, manufacturing commercial launch quantities adequate to meet market demand, and, where appropriate, paying and receiving consideration for selective waiver and/or relinquishment of 180-day first-to-file marketing exclusivities.

143. Defendants' Exclusion Payment Agreements, which delayed introduction into the United States marketplace of generic versions of Nexium, have caused Plaintiffs and the Class to pay more than they would have paid for delayed-release esomeprazole magnesium absent Defendants' illegal conduct.

144. Typically, generic versions of brand name drugs are initially priced significantly below the corresponding branded drug to which they are AB-rated. As a result, upon generic entry, end-payors rapidly substitute generic versions of the drug for some or all of their purchases. As more generic manufacturers enter the market, prices for generic versions of a drug predictably plunge even further due to competition among the generic manufacturers, and, correspondingly, the brand name drug loses even more of its market share to the generic versions of the drug. This price competition enables all purchasers of the drugs to: (a) purchase generic versions of a drug at substantially lower prices, and/or (b) purchase the brand name drug at a reduced price. Consequently, brand name drug manufacturers have a keen financial interest in delaying the onset of generic competition, and purchasers experience substantial cost inflation from that delay.

145. But for the Exclusion Payment Agreements, end-payors, such as Plaintiffs and members of the Class, would have paid less for delayed-release esomeprazole magnesium by (a) substituting purchases of less-expensive AB-rated generic Nexium for their purchases of more-expensive branded Nexium, (b) receiving discounts on their remaining branded Nexium purchases, and (c) purchasing generic Nexium at lower prices sooner.

146. Moreover, due to Defendants' Exclusion Payment Agreements and the overarching scheme alleged herein, other generic manufacturers were discouraged from and/or

delayed in (a) developing generic versions of Nexium, and/or (b) challenging the validity or infringement of the Nexium patents in court.

147. During the Class Period, Plaintiffs and other members of the Class purchased substantial amounts of Nexium. As a result of Defendants' illegal conduct as alleged herein, Plaintiffs and other members of the Class were compelled to pay, and did pay, artificially inflated prices for delayed-release esomeprazole magnesium. Plaintiffs and the other Class members paid prices for delayed-release esomeprazole magnesium that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein, because: (1) Class members were deprived of the opportunity to purchase lower-priced generic Nexium instead of expensive brand-name Nexium; and (2) Class members paid artificially inflated prices for delayed-release esomeprazole magnesium.

148. As a consequence, Plaintiffs and other members of the Class have sustained substantial losses and damage to their business and property in the form of overcharges, the exact amount of which will be the subject of proof at trial.

149. Thus, Defendants' unlawful conduct deprived Plaintiffs and the Class of the benefits of competition that the antitrust laws were designed to ensure.

VII. ANTITRUST IMPACT

150. During the relevant period, Plaintiffs and members of the Class purchased substantial amounts of Nexium indirectly from Defendants and/or purchased substantial amounts of AB-rated Nexium bioequivalent generic indirectly from Defendants or others. As a result of Defendants' illegal conduct, members of the End-Payor Class were compelled to pay, and did pay, artificially inflated price for their delayed-release esomeprazole magnesium requirements. Those prices were substantially greater than the prices that members of the Class would have paid absent the illegal conduct alleged herein, because: (1) the price of brand-name Nexium was

artificially inflated by Defendants' illegal conduct, (2) Class members were deprived of the opportunity to purchase lower-priced generic versions of Nexium, and/or (3) the price of AB-rated Nexium generic (delayed-release esomeprazole magnesium) was artificially inflated by Defendants' illegal conduct.

151. As a consequence, Plaintiffs and members of the Class have sustained substantial losses and damage to their business and property in the form of overcharges. The full amount and forms and components of such damages will be calculated after discovery and upon proof at trial.

152. General economic theory recognizes that any overcharge at a higher level of distribution generally results in higher prices at every level below.

153. Wholesalers and retailers passed on the inflated prices of Nexium and AB-rated generic Nexium to the End-Payors defined herein.

154. AstraZeneca's anticompetitive actions enabled it to indirectly charge consumers and third-party payors prices in excess of what it otherwise would have been able to charge absent its unlawful actions individually and with Generic Manufacturers.

155. The prices were inflated as a direct and foreseeable result of AstraZeneca's anticompetitive conduct individually and with Generic Manufacturers.

156. The inflated prices the End-Payor Class paid are traceable to, and the foreseeable result of, the overcharges by AstraZeneca and the Generic Manufacturers.

VIII. CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF
For Monopolization Under State Law
(Asserted Against AstraZeneca)

157. Plaintiffs hereby repeat and incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

158. At all relevant times, AstraZeneca possessed substantial market power (*i.e.*, monopoly power) in the relevant market. AstraZeneca possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.

159. Through the overarching anticompetitive scheme, as alleged extensively above, AstraZeneca willfully maintained its monopoly power in the relevant market using restrictive or exclusionary conduct, rather than by means of greater business acumen, in order to exclude competition for Nexium.

160. The goal, purpose, and effect of AstraZeneca's scheme was to prevent and delay the sale of generic Nexium products in the United States at prices significantly below AstraZeneca's prices for Nexium, thereby effectively preventing the average market price of delayed-release esomeprazole magnesium products from declining dramatically.

161. By engaging in the foregoing conduct, AstraZeneca has intentionally and wrongfully maintained monopoly power in the relevant market in violation of the following state laws:

a. Arizona Rev. Stat. §§ 44-1403, *et seq.*, with respect to purchases in Arizona by members of the Class.

b. Cal. Bus. & Prof. Code §§ 17200, *et seq.*, with respect to purchases in California by members of the Class.

c. D.C. Code §§ 28-4503, *et seq.*, with respect to purchases in the District of Columbia by members of the Class.

d. Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases in Florida by members of the Class.

e. 740 Ill. Comp. Stat. 10/3, *et seq*., with respect to purchases in Illinois by members of the Class.

f. Iowa Code § 553.5 et seq., with respect to purchases in Iowa by members of the Class.

g. Mass. Gen. L. Ch. 93A, et seq., with respect to purchases in Massachusetts by members of the Class, with thousands of Massachusetts end-payors paying substantially higher prices for Nexium and AB-rated bioequivalents in actions and transactions occurring substantially within Massachusetts.

h. Me. Rev. Stat. Ann. 10, §§ 1102, *et seq.*, with respect to purchases in Maine by members of the Class.

i. Mich. Comp. Laws Ann. §§ 445.773, *et seq.*, with respect to purchases in Michigan by members of the Class.

j. Minn. Stat. §§ 325D.52, *et seq.*, and Minn. Stat. § 8.31, *et seq.*, with respect to purchases in Minnesota by members of the Class.

k. Miss. Code Ann. §§ 75-21-3, *et seq.*, with respect to purchases in Mississippi by members of the Class.

l. Neb. Code Ann. §§ 59-802, *et seq.*, with respect to purchases in Nebraska by members of the Class.

m. Nev. Rev. Stat. Ann. §§ 598A.060, *et seq.*, with respect to purchases in Nevada by members of the Class.

n. N.M. Stat. Ann. §§ 57-1-2, *et seq.*, with respect to purchases in New Mexico by members of the Class.

o. N.C. Gen. Stat. §§ 75-2.1, *et seq.*, with respect to purchases in North Carolina by members of the Class.

p. N.D. Cent. Code §§ 51-08.1-03, *et seq.*, with respect to purchases in North Dakota by members of the Class.

q. 10 L.P.R.A. § 260, et seq., with respect to purchases in Puerto Rico by members of the Class.

r. S.D. Codified Laws §§ 37-1-3.2, *et seq.*, with respect to purchases in South Dakota by members of the Class.

s. Vt. Stat. Ann. 9, §§ 2453, *et seq.*, with respect to purchases in Vermont by members of the Class.

t. W.Va. Code §§ 47-18-4, *et seq.*, with respect to purchases in West Virginia by members of the Class.

u. Wis. Stat. §§ 133.03, *et seq.*, with respect to purchases in Wisconsin by members of the Class.

162. Plaintiffs and members of the Class have been injured in their business or property by reason of AstraZeneca's antitrust violations alleged in this Claim. Their injuries consist of: (1) being denied the opportunity to purchase lower-priced generic delayed-release esomeprazole magnesium products, and (2) paying higher prices for delayed-release esomeprazole magnesium products than they would have paid in the absence of AstraZeneca's conduct. These injuries are of the type the laws of the above States, the District of Columbia, and Puerto Rico were designed to prevent, and flow from that which makes Defendants' conduct unlawful.

163. Plaintiffs and the Class seek damages and multiple damages as permitted by law for their injuries by AstraZeneca's violations of the aforementioned statutes.

SECOND CLAIM FOR RELIEF
For Attempted Monopolization Under State Law
(Asserted Against AstraZeneca)

164. Plaintiffs hereby repeat and incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

165. AstraZeneca possesses substantial market power (i.e., monopoly power) in the relevant market. AstraZeneca possesses the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market. Alternatively, AstraZeneca possesses a dangerous probability of achieving monopoly power in the relevant market.

166. With the specific intent to achieve a monopoly, AstraZeneca acquired and willfully maintained its monopoly power in the relevant market using restrictive or exclusionary conduct, rather than by means of greater business acumen, in order to exclude competition for Nexium.

167. The goal, purpose, and effect of AstraZeneca's scheme was to prevent and delay the sale of generic Nexium products in the United States at prices significantly below AstraZeneca's prices for Nexium, thereby effectively preventing the average market price of delayed-release esomeprazole magnesium products from declining dramatically.

168. By engaging in the foregoing conduct, AstraZeneca has intentionally and wrongfully attempted to monopolize the relevant market in violation of the following state laws:

a. Arizona Rev. Stat. §§ 44-1403, et seq., with respect to purchases in Arizona by members of the Class.

b. Cal. Bus. & Prof. Code §§ 17200, et seq., with respect to purchases in California by members of the Class.

c. D.C. Code §§ 28-4503, et seq., with respect to purchases in the District of Columbia by members of the Class.

d. Fla. Stat. §§ 501.201, et seq., with respect to purchases in Florida by members of the Class.

e. 740 Ill. Comp. Stat. 10/3, et seq., with respect to purchases in Illinois by members of the Class.

f. Iowa Code § 553.5 et seq., with respect to purchases in Iowa by members of the Class.

g. Mass. Gen. L. Ch. 93A, et seq., with respect to purchases in Massachusetts by members of the Class, with thousands of Massachusetts end-payors paying substantially higher prices for Nexium and AB-rated bioequivalents in actions and transactions occurring substantially within Massachusetts.

h. Me. Rev. Stat. Ann. 10, §§ 1102, et seq., with respect to purchases in Maine by members of the Class.

i. Mich. Comp. Laws Ann. §§ 445.773, et seq., with respect to purchases in Michigan by members of the Class.

j. Minn. Stat. §§ 325D.52, et seq., and Minn. Stat. § 8.31, et seq., with respect to purchases in Minnesota by members of the Class.

k. Miss. Code Ann. §§ 75-21-3, et seq., with respect to purchases in Mississippi by members of the Class.

l. Neb. Code Ann. §§ 59-802, et seq., with respect to purchases in Nebraska by members of the Class.

m. Nev. Rev. Stat. Ann. §§ 598A.060, et seq., with respect to purchases in Nevada by members of the Class.

n. N.M. Stat. Ann. §§ 57-1-2, et seq., with respect to purchases in New Mexico by members of the Class.

o. N.C. Gen. Stat. §§ 75-2.1, et seq., with respect to purchases in North Carolina by members of the Class.

p. N.D. Cent. Code §§ 51-08.1-03, et seq., with respect to purchases in North Dakota by members of the Class.

q. 10 L.P.R.A. § 260, et seq., with respect to purchases in Puerto Rico by members of the Class.

r. S.D. Codified Laws §§ 37-1-3.2, et seq., with respect to purchases in South Dakota by members of the Class.

s. Vt. Stat. Ann. 9, §§ 2453, et seq., with respect to purchases in Vermont by members of the Class.

t. W.Va. Code §§ 47-18-4, et seq., with respect to purchases in West Virginia by members of the Class.

u. Wis. Stat. §§ 133.03, et seq., with respect to purchases in Wisconsin by members of the Class.

169. Plaintiffs and members of the Class have been injured in their business or property by reason of AstraZeneca's antitrust violations alleged in this Claim. Their injuries consist of: (1) being denied the opportunity to purchase lower-priced generic delayed-release

esomeprazole magnesium products, and (2) paying higher prices for delayed-release esomeprazole magnesium products than they would have paid in the absence of AstraZeneca's conduct. These injuries are of the type the laws of the above States, the District of Columbia and Puerto Rico were designed to prevent, and flow from that which makes Defendants' conduct unlawful.

170. Plaintiffs and the Class seek damages and multiple damages as permitted by law for their injuries by AstraZeneca's violations of the aforementioned statutes.

THIRD CLAIM FOR RELIEF
For Conspiracy to Monopolize Under State Law
(Asserted Against AstraZeneca and Ranbaxy; AstraZeneca and Teva; AstraZeneca and Dr. Reddy's, and All Defendants)

171. Plaintiffs hereby repeat and incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

172. At all relevant times, AstraZeneca possessed substantial market power (i.e., monopoly power) in the relevant market. AstraZeneca possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.

173. Through the overarching anticompetitve scheme, including the Exclusion Payment Agreements with Ranbaxy, Teva, and Dr. Reddy's, Defendants knowingly and intentionally conspired to maintain and enhance AstraZeneca's monopoly power in the relevant market by blocking and delaying market entry of delayed-release esomeprazole magnesium. The unlawful Exclusion Payment Agreements between Defendants allocated 100% of the delayed-release esomeprazole magnesium market in the United States; delayed the sales of generic Nexium products for as long as six years or more; and fixed the price at which consumers and other End-Payor Plaintiffs would pay for delayed-release esomeprazole magnesium at the higher, branded price.

174. The goal, purpose and/or effect of the Exclusion Payment Agreements was to maintain and extend AstraZeneca's monopoly power in the United States market for delayed-release esomeprazole magnesium. The Exclusion Payment Agreements prevented and/or delayed generic competition to Nexium and enabled AstraZeneca to continue charging supracompetitive prices for Nexium without a loss of sales sufficient to make those prices unprofitable.

175. Defendants specifically intended that the Exclusion Payment Agreements would maintain AstraZeneca's monopoly power in the relevant market, and injured Plaintiffs and the Class thereby.

176. Defendants each committed at least one overt act in furtherance of the conspiracy.

177. As a direct and proximate result of Defendants' unlawful restraint of trade and unlawful maintenance and conspiracy to maintain AstraZeneca's monopoly power, Plaintiffs and members of the Class paid artificially inflated prices for their delayed-release esomeprazole magnesium requirements as described herein, and were harmed as a result.

178. By engaging in the foregoing conduct, Defendants have intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of the following state laws:

a. Arizona Rev. Stat. §§ 44-1402, et seq., with respect to purchases in Arizona by members of the Class.

b. Cal. Bus. Code §§ 16700, et seq., with respect to purchases in California by members of the Class.

c. D.C. Code Ann. §§ 28-4503, et seq., with respect to purchases in the District of Columbia by members of the Class.

d. Fla. Stat. §§ 501.201, et seq., with respect to purchases in Florida by members of the Class.

e. 740 Ill. Comp. Stat. 10/3, et seq., with respect to purchases in Illinois by members of the Class.

f. Iowa Code § 553.3 et seq., with respect to purchases of Nexium and AB-rated generic equivalents in Iowa by members of the Class.

g. Kan. Stat. Ann. §§ 50-101, et seq., with respect to purchases in Kansas by members of the Class.

h. Mass. Gen. L. Ch. 93A, et seq., with respect to purchases in Massachusetts by members of the Class, with thousands of Massachusetts end-payors paying substantially higher prices for Nexium and AB-rated bioequivalents in actions and transactions occurring substantially within Massachusetts.

i. Me. Rev. Stat. Ann. 10, § 1101, et seq., with respect to purchases in Maine by members of the Class.

j. Mich. Comp. Laws Ann. §§ 445.772, et seq., with respect to purchases in Michigan by members of the Class.

k. Minn. Stat. §§ 325D.52, et seq., with respect to purchases in Minnesota by members of the Class.

l. Miss. Code Ann. §§ 75-21-3, et seq., with respect to purchases in Mississippi by members of the Class.

m. Neb. Code Ann. §§ 59-802, et seq., with respect to purchases in Nebraska by members of the Class.

n. Nev. Rev. Stat. Ann. § 598A.060, et seq., with respect to purchases in Nevada by members of the Class, in that thousands of sales of Nexium took place at Nevada pharmacies, purchased by Nevada end-payors at supracompetitive prices caused by Defendants' conduct.

o. N.M. Stat. Ann. §§ 57-1-2, et seq., with respect to purchases in New Mexico by members of the Class.

p. New York General Business Law § 340, et seq., with respect to purchases in New York by members of the Class.

q. N.C. Gen. Stat. §§ 75-2.1, et seq., with respect to purchases in North Carolina by members of the Class.

r. N.D. Cent. Code § 51-08.1-02, et seq., with respect to purchases in North Dakota by members of the Class.

s. 10 L.P.R.A. § 251, et seq., with respect to purchases in Puerto Rico by members of the Class.

t. S.D. Codified Laws Ann. § 37-1-3.2, et seq., with respect to purchases in South Dakota by members of the Class.

u. Tenn. Code Ann. §§ 47-25-101, et seq., with respect to purchases in Tennessee by members of the Class, in that the actions and transactions alleged herein substantially affected Tennessee, with thousands of end-payors in Tennessee paying substantially higher prices for Nexium and AB-rated generic equivalents at Tennessee pharmacies.

v. Vt. Stat. Ann. 9, § 2453, et seq., with respect to purchases in Vermont by members of the Class.

w. W.Va. Code §§ 47-18-3, et seq., with respect to purchases in West Virginia by members of the Class.

x. Wis. Stat. § 133.03, et seq., with respect to purchases of Nexium and AB-rated generic equivalents in Wisconsin by members of the Class, in that the actions and transactions alleged herein substantially affected the people of Wisconsin, with thousands of end-payors in Wisconsin paying substantially higher price for Nexium at Wisconsin pharmacies.

179. Plaintiffs and members of the Class have been injured in their business or property by reason of Defendants' antitrust violations alleged in this Claim. Their injuries consist of: (1) being denied the opportunity to purchase lower-priced generic delayed-release esomeprazole magnesium products, and (2) paying higher prices for delayed-release esomeprazole magnesium products than they would have paid in the absence of Defendants' conduct. These injuries are of the type the laws of the above States, the District of Columbia and Puerto Rico were designed to prevent, and flow from that which makes Defendants' conduct unlawful.

180. Plaintiffs and the Class seek damages and multiple damages as permitted by law for their injuries by Defendants' violations of the aforementioned statutes.

FOURTH CLAIM FOR RELIEF

For Conspiracy and Combination in Restraint of Trade Under State Law (Asserted Against AstraZeneca and Ranbaxy; AstraZeneca and Teva; AstraZeneca and Dr. Reddy's, and All Defendants)

181. Plaintiffs hereby incorporate each preceding and succeeding paragraph as though fully set forth herein.

182. In or about April 2008 and at times prior to the formal execution thereof AstraZeneca and Ranbaxy entered into the AstraZeneca/Ranbaxy Exclusion Payment Agreement, a continuing illegal contract, combination and conspiracy in restraint of trade under which AstraZeneca agreed to pay Ranbaxy substantial consideration in exchange for Ranbaxy's agreement to delay bringing its generic version of Nexium to the market, the purpose and effect of which were to: (a) allocate 100% of the market for delayed-release esomeprazole magnesium in the United States; (b) prevent the sale of generic versions of Nexium in the United States, thereby protecting Nexium from any generic competition for as long as 6 years or more; and c) fix the price at which end-payors would pay for delayed-release esomeprazole magnesium at supracompetitive levels.

183. Subsequently, in January 2010 and January 2011 respectively, AstraZeneca entered into additional unlawful Exclusion Payment Agreements with Teva and Dr. Reddy's. The purpose and effect of these additional Agreements was also to: (a) allocate 100% of the market for delayed-release esomeprazole magnesium in the United States; (b) prevent the sale of generic versions of Nexium in the United States, thereby protecting Nexium from any generic competition for as long as 6 years or more; and (c) fix the price at which end-payors would pay for delayed-release esomeprazole magnesium at supracompetitive levels.

184. The purpose and effect of the payments flowing from AstraZeneca to Generic Defendants under the Agreements was to delay generic competition to Nexium and there is no legitimate, nonpretextual, precompetitive business justification for the Exclusion Payments that outweighs their harmful effects. Nor were the payments or market restraining Agreement terms beyond the exclusionary reach of the relevant patents necessary to achieving any conceivable procompetitive purpose.

185. The Exclusion Payment Agreements covered a sufficiently substantial percentage of the relevant market to harm competition.

186. Defendants are per se liable for the Agreements or, in the alternative, are liable under a "quick look" rule of reason standard.

187. As a direct and proximate result of Defendants' unlawful restraint of trade and unlawful maintenance and conspiracy to maintain AstraZeneca's monopoly power, Plaintiffs and members of the Class paid artificially inflated prices for their delayed-release esomeprazole magnesium requirements as described herein, and were harmed as a result.

188. By engaging in the foregoing conduct, Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of the following state laws:

a. Arizona Rev. Stat. §§ 44-1402, et seq., with respect to purchases in Arizona by members of the Class.

b. Cal. Bus. Code §§ 16700, et seq., with respect to purchases in California by members of the Class.

c. D.C. Code Ann. §§ 28-4502, et seq., with respect to purchases in the District of Columbia by members of the Class.

d. Fla. Stat. §§ 501.201, et seq., with respect to purchases in Florida by members of the Class.

e. 740 Ill. Comp. Stat. 10/3, et seq., with respect to purchases in Illinois by members of the Class.

f. Iowa Code § 553.2 et seq. with respect to purchases in Iowa by members of the Class.

g. Kan. Stat. Ann. §§ 50-101, et seq., with respect to purchases in Kansas by members of the Class.

h. Mass. Gen. L. Ch. 93A, et seq., with respect to purchases in Massachusetts by members of the Class, with thousands of Massachusetts end-payors paying substantially higher prices for Nexium and AB-rated bioequivalents in actions and transactions occurring substantially within Massachusetts.

i. Me. Rev. Stat. Ann. 10, § 1101, et seq., with respect to purchases in Maine by members of the Class.

j. Mich. Comp. Laws Ann. §§ 445.772, et seq., with respect to purchases in Michigan by members of the Class.

k. Minn. Stat. §§ 325D.51, et seq., with respect to purchases of in Minnesota by members of the Class.

l. Miss. Code Ann. §§ 75-21-3, et seq., with respect to purchases in Mississippi by members of the Class.

m. Neb. Code Ann. §§ 59-801, et seq., with respect to purchases in Nebraska by members of the Class.

n. Nev. Rev. Stat. Ann. § 598A.060, et seq., with respect to purchases in Nevada by members of the Class, in that thousands of sales of Nexium took place at Nevada pharmacies, purchased by Nevada end-payors at supracompetitive prices caused by Defendants' conduct.

o. N.M. Stat. Ann. §§ 57-1-1, et seq., with respect to purchases in New Mexico by members of the Class.

p. New York General Business Law § 340, et seq., with respect to purchases in New York by members of the Class.

q. N.C. Gen. Stat. §§ 75-1, et seq., with respect to purchases in North Carolina by members of the Class.

r. N.D. Cent. Code § 51-08.1-02, et seq., with respect to purchases in North Dakota by members of the Class.

s. 10 L.P.R.A. § 251, et seq., with respect to purchases in Puerto Rico by members of the Class.

t. S.D. Codified Laws Ann. § 37-1-3.2, et seq., with respect to purchases in South Dakota by members of the Class.

u. Tenn. Code Ann. §§ 47-25-101, et seq., with respect to purchases in Tennessee by members of the Class, in that the actions and transactions alleged herein substantially affected Tennessee, with thousands of end-payors in Tennessee paying substantially higher prices for Nexium and AB-rated generic equivalents at Tennessee pharmacies.

v. Vt. Stat. Ann. 9, § 2453, et seq., with respect to purchases in Vermont by members of the Class.

w. W.Va. Code §§ 47-18-3, et seq., with respect to purchases in West Virginia by members of the Class.

x. Wis. Stat. § 133.03, et seq., with respect to purchases in Wisconsin by members of the Class, in that the actions and transactions alleged herein substantially affected the people of Wisconsin, with thousands of end-payors in Wisconsin paying substantially higher price for Nexium at Wisconsin pharmacies.

189. Plaintiffs and members of the Class have been injured in their business or property by reason of Defendants' antitrust violations alleged in this Claim. Their injuries consist of: (1) being denied the opportunity to purchase lower-priced generic delayed-release esomeprazole magnesium products, and (2) paying higher prices for delayed-release esomeprazole magnesium products than they would have paid in the absence of Defendants' conduct. These injuries are of the type the laws of the above States, the District of Columbia, and Puerto Rico were designed to prevent, and flow from that which makes Defendants' conduct unlawful.

190. Plaintiffs and the Class seek damages and multiple damages as permitted by law for their injuries by Defendants' violations of the aforementioned statutes

FIFTH CLAIM FOR RELIEF
Declaratory and Injunctive Relief Under Section 16 of the Clayton Act for Defendants' Violations of Sections 1 and 2 of the Sherman Act
(Asserted Against All Defendants)

191. Plaintiffs hereby incorporate each preceding and succeeding paragraph as though fully set forth herein.

192. Plaintiffs' allegations described herein and in the preceding Counts comprise violations of Sections 1 and 2 of the Sherman Act, in addition to the state laws *supra*.

193. Plaintiffs and the Class, pursuant to Fed. R. Civ. P. 57 and 28 U.S.C. § 2201(a) hereby seek a declaratory judgment that Defendants' conduct in seeking to prevent competition as described herein violates Sections 1 and 2 of the Sherman Act.

194. Plaintiffs and the Class further seek equitable and injunctive relief pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, and other applicable law, to correct for the anticompetitive market effects caused by the unlawful conduct of Defendants, and other relief so as to assure that similar anticompetitive conduct does not reoccur in the future.

IX. DEMAND FOR JUDGMENT

WHEREFORE, Plaintiffs, on behalf of itself and the End-Payor Class, demand judgment for the following relief:

A. Determine that this action may be maintained as a class action pursuant to Fed. R. Civ. P. 23(a) and (b)(3), and direct that reasonable notice of this action, as provided by Fed. R. Civ. P. 23(c)(2), be given to the Class and declare the Plaintiff representative of the End-Payor Class;

B. Declare that the conduct alleged herein is in violation of the statutes set forth above;

C. Enjoin Defendants from continuing the illegal activities alleged herein;

D. Enter joint and several judgments against Defendants in favor of Plaintiff and the End-Payor Class;

E. Award the End-Payor Class damages and, where applicable, treble, multiple, punitive, and/or other damages, in an amount to be determined at trial, including interest;

F. Award Plaintiffs and the End-Payor Class their costs of suit, including reasonable attorneys' fees as provided by law; and

G. Grant such other further relief as is necessary to correct for the anticompetitive market effects caused by the unlawful conduct of Defendants, and as the Court deems just.

X. JURY DEMAND

Pursuant to Fed. Civ. P. 38, Plaintiffs on behalf of itself and the proposed Class demand a trial by jury on all issues so triable.

Dated: January 22, 2013

Respectfully submitted,

/s/ Glen DeValerio

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CERTIFICATE OF SERVICE

I, Glen DeValerio, hereby certify that this document, filed through the ECF system, will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF), and paper copies will be sent to those indicated as non-registered participants on January 22, 2013.

/s/ Glen DeValerio
Glen DeValerio